



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,138	10/15/2003	Brian J. Brown	S13.12-0145	6236

38356 7590 10/17/2006

BROOKS & CAMERON, PLLC
1221 NICOLLET MALL #500
MINNEAPOLIS, MN 55403

EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,138

Applicant(s)

BROWN ET AL.

Examiner

Melanie Tyson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/04 & 5/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species I in the reply filed on 14 September 2006 is acknowledged. The traversal is on the ground(s) that the examination of the entire application can be made without serious burden. This is not found persuasive because Species I-V are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). Species I comprises a marker forming a conductive loop or plurality of windings on a strut, Species II comprises a marker forming a cube, Species III comprises a marker forming a hollow sphere, Species IV comprises a plurality of conductive windings disposed about the periphery of a strut and a connector, and Species IV comprises a marker formed of multiple coils connected together. Therefore, the related inventions as claimed do not overlap in scope, i.e., are mutually exclusive. Since the related inventions do not overlap in scope, different search queries would be employed, thus requiring a different field of search (see MPEP § 808.02), which places a serious burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. All claims have been examined. Contrary to applicant's remark, claims 11 and 21 read on elected species I since applicant states on page 9 of the specification that the

Art Unit: 3731

marker of Species I may be printed on a strut or a connector. Applicant timely traversed the restriction (election) requirement in the reply filed on 14 September 2006.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include reference numbers 19 and 21 mentioned on page 9, line 15, of the description and Figure 1 includes reference number 5, which is not mentioned in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 6, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5, 6, and 12 recite the limitation "the

opening.” There is insufficient antecedent basis for this limitation in the claim. For examination purposes, claims 5 and 6 have been interpreted as being dependent on claim 4, and claim 16 has been interpreted as being dependent on claim 15.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Melzer et al. (Patent No. 6,280,385 B1). Melzer et al. disclose a device (Figure 6, element 1) that includes all the limitations of claims 1-8, 11, and 13-18. The device (1') includes: tubular structure (or stent) formed of plastic (column 6, lines 48-51) and an RF marker (resonance circuit, column 3, lines 31-32; woven, column 10, lines 39-44) configured to emit RF energy (column 3, lines 31-40). Figure 6 shows the RF marker comprises a loop (coil 5 having multiple loops of conductive material; column 9, lines 26-31) about an opening (about the circumference along the entire stent, where the circumference of the stent includes a lumen through the center of the entire stent, as well as multiple openings between struts). Since the multi-loop winding disclosed by Melzer et al. generate RF energy under magnetic fields, it is inherent that two of the loops are oriented relative to one another to generate RF energy under magnetic fields that are applied in different directions. Furthermore, since the device disclosed by Melzer et al. is visibly detected under MRI, it is inherent that the RF marker emits

Art Unit: 3731

sufficient energy under MRI visualization to disturb hydrogen atom spins of at least one voxel.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 9, 19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melzer et al.

The device disclosed by Melzer et al. is formed of plastic (column 6, lines 48-51), has an RF marker coupled to it (column 10, lines 39-44), is designed to be implanted in a body cavity (column 6, lines 47-59), induces a signal equal to the resonance frequency applied by an MRI system (column 3, lines 31-37), and provides a magnetic resonance image (column 3, lines 44-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to implement the steps

Art Unit: 3731

claimed utilizing the device disclosed by Melzer et al. in order to clearly recognize the position of the device (column 3, lines 20-25 and 37-47), thus facilitating implantation.

Furthermore, Melzer et al. do not disclose the multi-loop winding is embedded in the tubular structure. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to embed the multi-loop winding in the tubular structure. Applicant has not disclosed that embedding the winding in the tubular structure provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well coupled to the tubular structure as disclosed by Melzer et al. because the function of the winding is to emit RF energy under the influence of an MRI system, and this function is not affected by the process used to attach the marker to the tubular structure. Therefore, it would have been obvious to modify the device of Melzer et al. to obtain the invention as specified in claims 9 and 19.

11. Claims 10-12, 20-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melzer et al. in view of Jackson et al. (Publication No. U.S. 2003/0004563 A1).

The tubular structure (or stent) of Melzer et al. is comprised of multiple struts (not labeled), and the RF marker is coupled to the struts of the tubular structure. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to embed the multi-loop winding disclosed by Melzer et al. in a strut for the same reasons given above (see paragraph 10). Melzer et al. do not disclose the tubular structure comprises connectors. Jackson et al. disclose a tubular structure (Figure 6)

Art Unit: 3731

comprising struts (not labeled) connected by connectors (52). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to connect the struts of Melzer with connectors as taught by Jackson et al. in order to provide a stent with longitudinal flexibility (paragraph 27).

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to embed the multi-loop winding in a connector, in a stent where connectors are provided as disclosed by Melzer et al. in view of Jackson et al. It is obvious that the RF marker disclosed by Melzer et al. in view of Jackson et al. would also be coupled to connectors since the marker extends along the entire stent. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to embed the multi-loop winding disclosed by Melzer et al. in view of Jackson et al. in a connector for the same reasons given above (see paragraph 10).

Jackson et al. also disclose a magnetic susceptibility marker connected to a generally tubular structure (stent). It would have been obvious to one of ordinary skill in the art at the time the invention was made to connect a magnetic marker to the tubular structure as taught by Jackson et al. in order to provide a structure that is visible using MRI and x-ray based fluoroscopy procedures (paragraph 12). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to implement the steps as claimed utilizing the device of Melzer et al. in view of Jackson et al. in order to clearly recognize the position of the device (Melzer et al., column 3, lines 20-25 and 37-47; Jackson et al. paragraph 16), thus facilitating implantation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
October 4, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/14/06